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10/563,586	12/13/2006	Jean Krutmann	7290-105	3304

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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,586	KRUTMANN, JEAN	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 5/23/2008. Claims 1-10 have been cancelled, and claims 11-19 have been added. Accordingly, claims 11-19 are pending and examined on the merits herein.

WITHDRAWN REJECTIONS

1. In view of Applicant's cancellation of claims 1-10, the objection of claims 3-10 for being improper multiple dependent claims is herein withdrawn.

2. In view of Applicant's cancellation of claims 1-10, rejections of these claims under 35 U.S.C. 112 for being indefinite and under 35 U.S.C. 101 are herein withdrawn.

NEW REJECTIONS

3. In light of Applicant's newly added claims, the following rejections have been newly added:

Claim Objections

4. Claim 12 objected to because of the following informalities: 1,3-dimmanosyl myo-inositol phosphate is recited as "1,3dimmanosyl myo-inositol phosphate" which is missing a dash between the "3" and "dimmanosyl." Appropriate correction is required.

Claim Rejections - 35 USC § 112

Written Description Rejection

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the instant specification does not give support for the embodiments of claims 11 and 14-19 that comprise osmolytes not found in extremophilic bacteria.

The instant specification broadly defines osmolytes as "low-molecular organic substances or compatible solutes" and lists examples of osmolytes that have been identified in extremophilic microorganisms, i.e. ectoine, hydroxyectoine, firoin, firoin-A, etc. The description of osmolytes found in extremophilic bacteria would not have put the Applicant in possession of common structural attributes or other features shared by members of the genus that would distinguish the osmolytes form other materials at the time of filing because, the single, disclosed subgenus (osmolytes found in extremophilic microorganisms) is not representative of the entire genus of osmolytes in general, and the instant specification does not disclose structural features shared by members of the genus, or guidance on how to determine osmolytes not belonging to said subgenus.

Thus, the description of osmolytes found in extremophilic microorganisms is not sufficient to describe the claimed genus of osmolytes. Accordingly, the instant specification is lacking sufficient written description to support the genus disclosed in the instant claims 11 and 14-19 because, the instant specification does not provide a representative number of species or common structural features to show that the Applicant would have been in possession of the claimed genus as a whole at the time of filing.

Second Paragraph Rejection

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "microsomally capsuled" is unclear. The specification does not provide a definition or any further clarification of this term.

For examination purposes and in the interest of compact prosecution, "microsomally capsuled" will be interpreted as liposomally capsuled, meaning the osmolyte is contained within a liposome.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauermann (DE 10133202 A1). US 20004/0220137 A1 is used as the English language equivalent.

Sauermann teaches the use of one ore more osmolytes or derivatives thereof in cosmetic or dermatological preparations to be topically applied for the treatment and prevention of deficient, sensitive, or hypoactive conditions of the skin, inflamed skin conditions, and of atopic eczema (neurodermatitis) (see abstract; page 3, sections [0044]-[0049]). Sauermann further teaches the cosmetic and dermatological preparations may exist in a variety of forms, such as O/W emulsions, W/O emulsions, or ointments, wherein said compositions may comprise cosmetic auxiliaries conventional used in such preparations (see pages 4-5, sections [0098] and [0102]). The cosmetic and dermatological preparations may also comprise antioxidants as additionally active agents, such as EDTA and derivatives thereof (i.e. salts) (see page 5, section [0105]). Sauermann teach examples of O/W creams that contain osmolytes such as myoinositol, taurine, or phosphatidylinositol, cosmetic auxiliaries such as dyes/perfumes, and antioxidants such as trisodium EDTA as an additional active ingredient (see page 11, Examples 1-5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauermann (DE 10133202 A1). US 20004/0220137 A1 is used as the English language equivalent.

Sauermann is described *supra* as applied to claims 11, 14, and 17. Sauermann further teaches that it is advantageous to administer the active he active ingredients (the osmolytes) in encapsulated form such as liposomally encapsulates (see page 5, section [0102]).

Sauermann does not explicitly teach a preparation wherein the osmolytes are liposomally encapsulated, or wherein flexible liposomes contain the osmolyte as

claimed in the instant claims 15 and 16 as best understood (see 112, 2nd paragraph rejection).

It would have been obvious to one of ordinary skill in the art at the time of the invention to contain the osmolyte active ingredient within a lipsome as taught by Sauermann. One of ordinary skill in the art would have been motivated to do with a reasonable expectation of success in doing because Sauermann teaches encapsulation of the osmolyte is advantageous, and lists liposomally encapsulated as a possible embodiment. Furthermore, it is the position of the Examiner, that liposomes are inherently flexible.

Thus, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time it was made.

10. Claims 11-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US 2004/0053860 A1).

The instant claims are directed to methods of treating neurodermatitis comprising topical application of a dermatological preparation comprising an osmolyte such as ectoine or hydroxyectoine (instant claims 12-13), or pharmacologically compatible salt thereof, wherein said preparation comprises a tincture, lotion, O/W emulsion, W/O emulsion, cream, ointment, hydrogel, or spray comprising auxiliary substances (instant claim 14). The preparation also contains additional active agents such as glucocorticoids (instant claims 17-19).

Buchholz et al. teach the use of flavonoid derivatives for the preparation of cosmetic, dermatological, or pharmaceutical suitable for topical application, suitable for the prevention and/or treatment of eczema, particularly atopic eczema (also referred to as endogenous eczema and neurodermatitis) (see abstract; page 1, section [0004]; page 3, section [0026]; page 4, section [0034]). Buchholz further teach that the formulations may further comprise ectoin, and that formulations comprising ectoin and tiliroside (a flavonoid derivative) are particularly advantageous (see page 13, section [0014). Buchholz et al. explicitly teach an example of an O/W cream comprises ectoin and tiliroside, *inter alia* (see page 17, Example 4). Hydroxyectoin is also listed as a possible active ingredient (see page 13, section [0015]-[0016]). Bocholt et al. also teach glucocorticoids may optionally be present in the preparation comprising flavonoids for their inflammation inhibiting action (see pages 3-4, sections [0027]-[0031] and [0033]-[0035]).

Buchholz et al. do not explicitly teach treating neurodermatitis comprising topical application of a dermatological preparation comprising an osmolyte (i.e. ectoin). Buchholz et al. also do not teach preparations comprising an osmolyte and an active agent (i.e. glucocorticoid, or flavonoid) for topical application in a method for treating neurodermatitis as claimed in the instant claims 17-19.

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat neurodermatitis by topically applying the composition comprising ectoin (an osmolyte) and tiliroside (an additional active agent) taught by Buchholz et al. One of ordinary skill in the art would have been motivated to do so with a reasonable

expectation of success because Buchholz et al. teach the compositions are suitable for topical application and intended for use in the prevention and/or treatment of atopic eczema (neurodermatitis).

In regards to claim 19, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a glucocorticoid as taught by Buchholz et al. to the composition comprising ectoin and tiliroside taught by Buchholz. One of ordinary skill in the art would have been motivated to do to provide the inflammation inhibiting action of the glucocorticoid. One of ordinary skill in the art would have had a reasonable expectation of success in doing so because Buchholz et al. clearly teach that one or more further active ingredients can be added to the composition comprising the flavonoid derivative, and lists glucocorticoids, ectoin, and hydroxyectoin as additional active agents.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art.

Response to Arguments

Applicant's responses with respect to claims 11-19 have been considered but are moot in view of the new ground(s) of rejection.

Comment [J1]: The Applicant's only response is that no issues remain and the claims are all in condition for allowance. They don't really make any arguments per se.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Bünger et al. (US 6,602,514 B1) teach topical compositions comprising ectoine or ectoine derivatives.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617